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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,683	01/31/2002	Mark Christopher Doyle	263/185	2180

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/062,683	<b>Applicant(s)</b> DOYLE ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003 and 26 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 21-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/29/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 15, lines 1-2, recites that the collar is a "C" shaped collar. However, claim 15 depends from claim 12, and claim 12, line 2, recites that the collar is annular. Annular means: of, relating to, or forming a ring. A "C" shape is not annular since it is not of, relating to, or forming a ring. Thus, an element cannot be both annular and "C" shaped. Therefore it is unclear as to whether the collar is annular or "C" shaped in claim 15, or stated another way, it is unclear as to what Applicant means by "C" shaped.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutson, 5,242,416.

As to claims 1 and 21-29, Hutson discloses a body (102) having an open proximal end and a distal end having an opening through which a needle and needle protector cap may extend, see Figure 1; a shield (104) having proximal and distal ends, the distal end having an opening as claimed, the shield being slidably attached to the body, and slidable between an unguarded and guarded position wherein the needle is covered by the shield; one or more tabs (106, 108) in a wall of one of the body and shield, the one or more tabs being deflectable from a first position wherein the tab extends along the wall or radially outwardly from the wall, to a second position wherein the tab is directed inwardly into the cavity (column 7, lines 26-28); and one or more detents (112) on the shield (column 7, line 55.)

As to claims 2, 3, 4, 5, 7, the tabs comprise a pair of tabs (106, 108) in opposing walls of the body, and being connected to the wall by a hinged region (figure 1.)

As to claim 6, a finger grip (60) on the proximal end of the body, the finger grip comprising a locking mechanism for engaging the proximal end of the syringe to limit axial movement of the syringe is disclosed (column 7, lines 16-19.)

As to claim 8, the syringe comprises a needle protector cap (62) and a barrel (52) as claimed.

As to claim 9, the shield comprises one or more openings (i.e., opening near 106 and 108) that overlie the one or more tabs when the shield is in the unguarded position (see Figure 1.)

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As to claims 10, 11, a syringe comprising a barrel (52) and a needle protector cap (118A, see figure 1 and column 7, line 68); and a radial element extending from the barrel is disclosed at (60); and a body (102), and a shield (104), as claimed is disclosed.

As to claim 12, the radial element (60) is a substantially annular collar having an outer diameter approximately as large as an outer diameter of the needle protector cap (118A.)

As to claim 15, since it is unclear as to what Applicant means by "C" shaped, the collar (60) is considered "C" shaped.

As to claims 16 and 17, the radial element (60) comprises a plurality of tabs extending from the barrel and disposed circumferentially about the barrel (i.e., the tabs are portions of the radial element integrally formed together.)

As to claim 18, a locking mechanism (106, 108) is disclosed on the proximal end of the body, the locking mechanism engaging a proximal end of the syringe to limit axial movement of the syringe.

As to claim 19, the locking mechanism (106, 108) comprises detents defining a slot, the slot receiving at least a portion of flange on the proximal end of the barrel therein to substantially secure the syringe within the cavity, see Figure 1.

As to claim 20, the syringe is a pre-filled syringe including medication therein, since the syringe is capable of being filled prior to usage.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutson, 5,242,416, in view Nathan et al., 5,833,660.

Hutson discloses the invention substantially as claimed (see above), except for the collar being secured to the barrel by adhesive, or being integrally molded as part of the barrel.

Nathan discloses a syringe having a syringe body (20) and a flange (21) that is integrally molded to the body (column 3, lines 1-2), or fabricated separately from the body and attached thereto with an adhesive (column 3, lines 4-5.)

It would have been obvious to one of ordinary skill in the art to form the flange on the Hutson syringe by integrally molding it onto the body of the syringe or fabricating it separately from the body and attaching it with an adhesive, as known and conventional means of constructing a syringe flange as taught by Nathan.

### ***Response to Arguments***

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Pace et al., 5,762,635, discloses an elongated flange with curved sides (see figure 3.) Frezza, 6,461,333, discloses a cap (22) having a diameter as large as the syringe flange (see figure 2.)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



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7/24/04